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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,633	06/26/2006	Takao Nakajima	00005.001297.	5585
5514 7590 08/18/2009 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA			EXAMINER	
			STOCKTON, LAURA LYNNE	
NEW YORK, NY 10112			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
	10/584,633	NAKAJIMA ET AL.		
Office Action Summary	Examiner	Art Unit		
	Laura L. Stockton	1626		
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
Responsive to communication(s) filed on <u>May</u> This action is <b>FINAL</b> . 2b) ☐ This     Since this application is in condition for alloware closed in accordance with the practice under E	action is non-final.  nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) 1-22,24-43 and 48-50 is/are pending 4a) Of the above claim(s) 5,6,15,19-21,28,29,3 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-4,7-14,16-18,22,24-27,30-35 and 3 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	<u>86,37 <i>and 48-50</i></u> is/are withdrawn	from consideration.		
Application Papers				
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the Edirawing(s) be held in abeyance. See tion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.				
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date See Continuation Sheet.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6) Other:	ate		

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : October 31, 2006, March 22, 2007 and June 26, 2009.

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#### DETAILED ACTION

Claims 1-22, 24-43 and 48-50 are pending in the application.

#### Election/Restrictions

Applicant's election of Group IV in the reply filed on May 8, 2009 is acknowledged.

**Group IV.** Claims 1-4, 7-14, 16-18, 24-27, 30-35 and 38-43 (in-part), drawn to products of formula (I) or formula (IA) or formula (IB) wherein  $\mathbf{R}^1$  is unsubstituted or substituted 5-membered aromatic heterocyclic group containing at least one oxygen atom;  $\mathbf{R}^2$  is  $-\mathrm{COR}^8$ ;  $\mathbf{R}^8$  is unsubstituted or substituted alicyclic heterocyclic group; one of  $\mathbf{R}^3$  and  $\mathbf{R}^4$  is  $\mathrm{COR}^{12}$  and the other is hydrogen or unsubstituted or substituted alkyl; and  $\mathbf{R}^{12}$  is unsubstituted or substituted aromatic heterocyclic group.

Because applicant did not distinctly and specifically point out the supposed errors in the

restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant has requested that the definition of the R<sup>12</sup> variable be expanded to also encompass compounds wherein  $R^{12}$  is a nonaromatic or nonheterocyclic group. In response, it is agreed that Group IV will be modified and examined to also embrace compounds wherein the  $\mathbf{R}^{12}$  variable represents substituted or unsubstituted cycloalkyl, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted alicyclic heterocyclic group, substituted or unsubstituted aromatic heterocyclic group, substituted or unsubstituted alicyclic heterocyclicalkyl or substituted or unsubstituted aromatic heterocyclic-alkyl. Modified Group IV embraces claims 1-4, 7-14, 16-18, 22, 24-27, 30-35 and 38-43.

The requirement is still deemed proper and is therefore made FINAL.

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Subject matter not embraced by elected Group IV and Claims 5, 6, 15, 19-21, 28, 29, 36, 37 and 48-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on May 8, 2009.

It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this Office Action.

## Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

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#### Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on October 31, 2006, March 22, 2007 and June 26, 2009.

### Specification

The amendment filed August 10, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment to page 512, lines 7-15; and the amendment to page 518, lines 21-23.

Applicant is required to cancel the new matter in the reply to this Office Action.

The amendment filed July 31, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment to page 33, line 30; the amendment to page 64, lines 17-23; the amendment to page 72, lines 17-21; the amendment to page 160, lines 6-7; the amendment page 221, lines 9-12; page 223, line 22 and ending at page 224, line 10; the amendment at page 224, lines 20-24; the amendment at page 229, lines 13-18; the amendment at page 232, lines 10-21; the amendment to page 247, lines 3-4; the amendment to page 249, lines 10-13; the amendment to page 258, lines 10-14; the amendment to page 264, line 30; the amendment to page 265, lines 16-30; the amendment to page 281, lines 13-25; the amendment to page 297, lines 19-23; the amendment to page 305, lines 6-22; the amendment to

age 306, lines 4-16; the amendment to page 311, lines 8-9; the amendment to page 327, lines 11-13; the amendment to page 329, lines 7-22; the amendment to page 322, lines 19-23; the amendment to page 339, lines 22-23; the amendment to page 350, lines 16-18; the amendment to page 377, lines 22-23; the amendment to page 389-28-29; the amendment to page 399, lines 15-18; the amendment to page 420, lines 3-14; the amendment to page 421, line 26 and ending at page 422, line 11; the amendment to page 423, lines 12-20; the amendment to page 455, lines 7-15; the amendment to page 472, lines 6-27; the amendment to page 473, line 26 ending at page 474, line 19; the amendment to page 480, lines 4-24; the amendment to page 481, lines 5-27; the amendment to page 482, lines 7-27; the amendment to page 515, line 10 and ending at page 516, line 3; the amendment to page 517, line 12 and ending at page 518; the amendment to page 518, line 27 ending at page 519, line 10; the amendment to page 535, lines 10-20; the amendment to

page 537, line 6 and ending at page 538, line 1; and the amendment to page 539, lines 19-22.

Applicant is required to cancel the new matter in the reply to this Office Action.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7-14, 16-18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because of the use of the term "general" which embraces unrecited compounds.

Therefore, the metes and bounds of the claims cannot be ascertained.

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#### Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-14, 16-18, 22, 24-27, 30-35 and 38-43 are provisionally rejected on the ground of

nonstatutory obviousness-type double patenting as being unpatentable over claims 4-8, 12 and 13 of copending Application No. 11/917,972. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically claimed in the copending application.

The indiscriminate selection of "some" among "many" is prima facie obvious, In re Lemin, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., antagonizing adenosine  $A_{2A}$  receptor).

One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful for antagonizing adenosine  $A_{2A}$  receptor. The instant claimed invention would have

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been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-14, 16, 17, 22, 24-27, 30-35, 38-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boigegrain et al. {U.S. Pat. 5,314,889}.

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# Determination of the scope and content of the prior art (MPEP \$2141.01)

al. (see entire document; particularly columns 1-4, 15, 16; and especially Example 30 in column 28 and Examples 35-37 in column 29) teach thiazole compounds that are structurally similar to the instant claimed compounds.

# Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

# Finding of prima facie obviousness--rational and motivation (MPEP \$2142-2413)

The indiscriminate selection of "some" among "many" is prima facie obvious, <u>In re Lemin</u>, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that

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structurally similar compounds would possess similar activity (e.g., gastric ulcers).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, gastric ulcers. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
Laura L. Stockton
Primary Examiner, Art Unit 1626
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August 18, 2009